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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/072,830	02/08/2002	Dong Feng Chen	ERM-105.01	2287

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EXAMINER

CHERNYSHEV, OLGA N

ART UNIT PAPER NUMBER

1646

DATE MAILED: 10/20/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/072,830

Applicant(s)

CHEN ET AL.

Examiner

Olga N. Chernyshev

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) 1-6, 10-21 and 25-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7-9 and 22-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group II in Paper No. 11 is acknowledged. The traversal is on the ground(s) that the examination of all groups would not require undue burden for the Examiner. This is not found persuasive because an application may properly be required to be restricted to one of two or more claimed inventions if they are able to support separate patents and they are either independent (MPEP § 806.04 - § 806.04 (j)) or distinct (MPEP § 806.05 - § 806.05 (i)). The Examiner has shown that the Groups I to VIII are independent or distinct for the reasons in the previous Office action (see Paper No. 9). Furthermore, MPEP § 803 provides that the separate classification (i.e., class and subclass) of distinct inventions is sufficient to establish a *prima facie* case that the search and examination of the plural inventions would impose a serious burden upon the Examiner; such separate classification was set forth in the Office action of Paper No. 9.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-6, 10-21 and 25-33 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 11.

Claims 7-9 and 22-24 are under examination in the instant office action.

Claim Objections

2. Claim 24 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the

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claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 24 encompasses a method for promoting axonal growth in a neuronal cell differentiated from a stem cell. It is well known in the art that any cell of a multicellular organism is differentiated from a stem cell at the early stage of embryonic development. See, for example, a review article by Tramontin et al. (Cerebral Cortex, 2003, Vol.13, No. 6, pp.580-587), which discloses that almost all of the cells in the developing mammalian brain are produced from neural stem cells (abstract, and section Introduction on page 580). Thus, the subject matter of claim 24 is of the same scope as the subject matter of claim 22, from which it depends.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 7, 8 and 22-24 are rejected under 35 U.S.C. 102(b) as being anticipated by Chen et al., 1999 (reference C-18 of IDS of Paper No. 8).

Claims 7, 8 and 22-24 are drawn to a method for promoting axonal growth in a neuronal cell by contacting the cell with an amount of lithium or salt thereof sufficient to stimulate axonal growth. Chen et al. disclose long term lithium treatment of primary *in vitro* cultures of cerebral granule cells, CGCs, which are CNS neural cells obtained from “a subject”, rat pups (see abstract

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and section Experimental Procedures, second column on page 6039). In the reference of Chen et al. CGCs were treated with 0.5-5 mM of LiCl, which is the same concentration of LiCl as disclosed in the instant specification (see page 59, line 22 of the instant specification). Thus, disclosure of Chen et al. anticipates instant claims 7, 8 and 22-23. Furthermore, because claim 24 encompasses a method for promoting axonal growth in a neuronal cell differentiated from a stem cell and because any neural cell is differentiated from a stem cell at the early stage of embryonic development (see Tramontin et al. and reasons of record in section 2 of the instant office action), claim 24 is anticipated by Chen et al.

Although reference of Chen et al. does not address axonal growth of the CGCs treated with LiCl, recognition by a persons of ordinary skill in the art is not required to show anticipation by inherency, see *Schering Corp. v. Geneva Pharmaceuticals, Inc.*, No. 02-1540 (Fed. Cir. Aug. 1, 2003), in which the CAFC affirmed the district court's decision and stated that the metabolite of the prior art loratadine of the '233 patent is the same compound that would necessarily be formed by the body when practicing the methods of administering loratadine disclosed in the '233 patent. Claims 1 and 3 of the '716 patent are invalidated and anticipated by the '233 patent by the inherent disclosure of DCL in the '233 patent.

Furthermore, the discovery of an inherent property of a prior art process can not serve as a basis for patenting that process. See *Ex parte Novitski*, 26 USPQ2d 1389 (Bd. Pat. App. & Inter. 1993) (The Board rejected a claim directed to a method for protecting a plant from plant pathogenic nematodes by inoculating the plant with a nematode inhibiting strain of *P. cepacia*. A U.S. patent to Dart disclosed inoculation using *P. cepacia* type Wisconsin 526 bacteria for protecting the plant from fungal disease. Dart was silent as to nematode inhibition but the Board

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concluded that nematode inhibition was an inherent property of the bacteria. The Board noted that applicant had stated in the specification that Wisconsin 526 possesses an 18% nematode inhibition rating.).

4. Claims 7, 9 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by Harada et al, 1996 (reference C-14 of IDS of Paper No. 8).

Claims 7, 9 and 22 are drawn to a method for promoting axonal growth in a neuronal cell by contacting the cell with an amount of lithium or salt thereof sufficient to stimulate axonal growth. Reference of Harada et al. describes treatment of PC12 cells, which are rat pheochromocytoma cells derived from adrenal gland and represent peripheral nervous system cells, with 0.1-3 mM LiCl (see page 197-198 and page 200, section Results). Thus, Harada et al. anticipate claims 7, 9 and 22 of the instant invention.

Although reference of Harada et al. does not address axonal growth of the PC12 cells treated with LiCl, recognition by a persons of ordinary skill in the art is not required to show anticipation by inherency, see reasons of record as applied to claims 7, 8 and 22-24 in section 3 of the instant office action.

Conclusion

5. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (703) 305-1003. The examiner can normally be reached on Monday to Friday 9 AM to 5 PM ET.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached on (703) 308-6564. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax center located in Crystal Mall 1 (CM1). The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers.

Official papers filed by fax should be directed to (703) 872-9306. If this number is out of service, please call the Group receptionist for an alternative number. Faxed draft or informal communications with the examiner should be directed to (703) 308-7939. Official papers should NOT be faxed to (703) 308-7939.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Olga N. Chernyshev, Ph.D.

